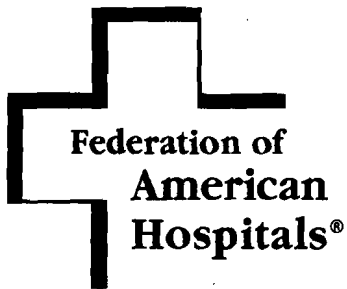


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Charles N. Kahn III
President

June 25, 2007

SENT VIA FACSIMILE AND U.S. MAIL

Ms. Carolyn Lovett
OMB Human Resources and Housing Branch
New Executive Office Building
Room 10235
Washington, DC 20503

RE: *CMS-R-131 (OMB#: 0938-0566); Agency Information Collection Activities: Proposed Collection; "Comment Request - Advance Beneficiary Notice of Noncoverage (ABN)"*

Dear Ms. Lovett:

The Federation of American Hospitals ("FAH") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural parts of the United States. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Notice, issued in accordance with the Paperwork Reduction Act of 1995, regarding the renewal of an agency information collection activity involving the Medicare Advance Beneficiary Notice of Noncoverage ("ABN"). (See 72 Fed. Reg. 29,322 (May 25, 2007).)

I. Combination of the Advance Beneficiary Notice and the Notice of Exclusion from Medicare Benefits

The proposed revisions to the ABN include combining the current General Use ABN (Form CMS-R-131-G) and the Laboratory Use ABN (Form CMS-R-131-L) into a single notice, called the Advance Beneficiary Notice of Noncoverage. In addition, according to the proposed form's instructions, this single general notice would be used in place of the Notice of Exclusion from Medicare

Benefits (NEMB) to provide voluntary notification of financial liability.¹ The FAH supports combining the Forms CMS-R-131-G and CMS-R-131-L, and appreciates the agency's action to streamline the ABN process to use one form.

However, for several reasons discussed below, we do not believe the ABN and NEMB forms and related processes should be combined. First, the instructions for the revised form state that notifiers "must complete the ABN as described below, and deliver the notice to the affected beneficiary..." This means that a completed ABN form is mandatory if a provider wishes to bill Medicare and hold the beneficiary liable should Medicare deny payment. Conversely, completion of the NEMB form for statutorily excluded services or services that do not meet the definition of a Medicare benefit is optional, and the provider may bill the beneficiary for such services even if an NEMB is not completed.

Also, the billing rules for statutorily excluded services (NEMB) and non-medically necessary services (ABN) are not equivalent. When an ABN is obtained for services that the provider does not believe are medically necessary, the provider must bill the services to Medicare in order for the Medicare Contractor to make a coverage determination. When reporting ABN services to Medicare, the services are listed as covered with occurrence code 32 and/or the GA modifier present on the claim. Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 1, §§ 60.1.2 and 60.4.1.

If a provider decides to obtain an NEMB for statutorily excluded services and the provider submits a claim to Medicare, the services are reported as non-covered with the GY modifier. The Medicare administrative contractor always will deny these services. Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 1, § 60.3.1.

If the forms are combined and both non-medically necessary and statutorily excluded services are included on the same ABN, the provider billing process would be more difficult, *e.g.*, determining which services require the GA modifier versus the GY modifier when both were on the same ABN. In addition, CMS billing rules state that ABN and demand billing should not be on the same claim. Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 1, § 60.3.1.

As a result, because the specific requirements for obtaining the two forms differ, we believe it is not reasonable to combine the forms and related billing processes, and doing so is likely to create confusion in the provider and beneficiary communities.

Accordingly, we believe that Option 2 should be removed from Section G of the proposed ABN form because it appears to apply only to statutorily excluded services.

If CMS decided to continue with its plan to combine the ABN and NEMB forms, the billing instructions for these two distinct types of items or services in the Medicare Claims Processing Manual, Chapter 1, Section 60 and Chapter 30, Section 90 will need to be revised. In accordance with revisions to these rules, Medicare claims processing systems also would need to be evaluated and potentially modified to process and adjudicate claims appropriately. Also, providers would need to implement system changes, develop new processes, and furnish extensive education.

The amount of time needed to publish new rules, update claims processing systems and conduct provider education should be considered when determining an effective date of the new ABN form. At

¹ It is also not clear from the proposed form and accompanying instructions whether the single general notice would replace the American Dental Association NEMB used for dental exclusions and the American Podiatric Medical Association NEMB used for foot care exclusions under Medicare. While these forms are not published by CMS, they are reviewed and approved by the agency and are used as part of the NEMB process.

a minimum, we estimate that this is likely to take as long as six months to accomplish. Therefore, if CMS decides to move forward with this proposal, we request a significant transition period to allow both providers and Medicare contractors to modify their operations to implement these changes.

II. Interpretive Rules To Implement the New ABN

The proposed Form Instructions for the Advance Beneficiary Notice of Noncoverage (ABN) state that:

[O]nce the new ABN approval process is completed, CMS will issue more detailed instructions on the use of the ABN in its on-line Medicare Claims Processing Manual, Publication 100-04, Chapter 30. In addition, note that related policy on billing and coding of claims, and as well as coverage determinations, is found elsewhere in the CMS manual system or website.

We request that CMS involve the provider community when developing the detailed instructions regarding use of the new ABN form. By doing so, CMS would be able to address provider questions and areas of confusion within the instructions versus leaving these areas open to provider interpretation.

We request that as CMS is developing the detailed instructions, that they also review the policies regarding billing and coding of claims that are found elsewhere in CMS materials to ensure that no conflicting information is disseminated.

For example, the following information is found in various material published by CMS regarding non-covered observation services:

ABNs may not be used to shift liability to a beneficiary in the case of services or items for which full payment is bundled into other payments; that is, where the beneficiary would otherwise not be liable for payment for the service or item because bundled payment is made by Medicare. Using an ABN to collect from a beneficiary where full payment is made on a bundled basis would constitute double billing. An ABN may be used to shift liability to a beneficiary in the case of services or items for which partial payment is bundled into other payments; that is, where part of the cost is not included in the bundled payment made by Medicare. (Medicare Claims Processing Manual, Chapter 30, Section 50.7.7.6 - ABNs and Bundled Payment)

Because observation is normally packaged and the additional hours over eight are packaged for separately payable observation, the above statements indicate that it would not be appropriate to obtain an ABN or NEMB and bill the beneficiary for the non-covered hours.

If a hospital intends to place or retain a beneficiary in observation for a noncovered service, it must give the beneficiary proper written advance notice of noncoverage under limitation on liability procedures (see Pub. 100-04, Medicare Claims Processing Manual; Chapter 30, "Financial Liability Protections," §20, at <http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf> for information regarding Limitation On Liability (LOL) Under §1879 Where Medicare Claims Are Disallowed). (Medicare Benefit Policy Manual, Chapter 6, Section 20.5 - Outpatient Observation Services)

The above guidelines suggest that we should be obtaining ABNs and billing the patient for noncovered observation.

In addition, current instructions in the Medicare Claims Processing Manual, Chapter 4, Section 290.5 - Services Not Covered as Observation Services state:

The hospital should bill for the period of medically necessary observation and should also submit non-covered services according to billing instructions in the Medicare Claims Processing Manual, Pub 100-04, Chapter 1, §60.1.2. Hospitals should submit a non-covered charge amount equal to the total charge for each service and should use modifier -GY or condition code 21 as appropriate.

These differing statements have resulted in various provider interpretations regarding the appropriateness of the use of ABNs for observation services.

III. Header

Regarding completion of the Header of the new ABN form, the instructions state: “*If appropriate, the name of more than one entity may be given in the notifier area, such as when the ordering and rendering providers differ, as long as this is clearly conveyed to the beneficiary for purposes of responding to questions.*”

Since the rendering provider is ultimately responsible for obtaining ABNs and billing Medicare for such services, we do not recommend that both the ordering and rendering providers be listed in the Header section. Listing both providers may be confusing to the beneficiary.

IV. Estimated Cost

Regarding Section F Estimated Cost, the instructions for the revised form state, “Notifiers must enter a cost estimate in this blank for the items or services described in Blank (D).” Form Instructions at p. 3. Current instructions (Medicare Claims Processing Manual, Chapter 30, Section 50.5.7) regarding Estimated Cost state:

The user may provide the patient with an estimated cost of the items and/or services. The patient may ask about the cost and jot down an amount in this space. Users should respond to such inquiries to the best of their ability. The lack of an amount on this line, or an amount which is different from the final actual cost, does not invalidate the ABN; an ABN will not be considered to be defective on that basis. In the case of an ABN which includes multiple items and/or services, it is permissible for the user to give estimated amounts for the individual items and/or services rather than an aggregate estimate of costs. Amounts may be provided either with the description of items and services or on the “Estimated Cost” line.

We would ask CMS to clarify whether the Estimated Cost is mandatory. In addition, we request that CMS define if an estimate is different from the actual cost, how much variance is allowed before the ABN would be considered defective. We also ask that CMS provide additional guidance regarding what constitutes a “good faith estimate.”

V. Options Box

The proposed instructions state:

If a beneficiary chooses to receive some, but not all of the items or services that are subject of the notice, the items and services in Blank (D) that they do not wish to receive may be crossed

out, if this can be done in a way that also clearly strikes the reason(s) and cost information in Blanks (E) and (F) that correspond to that care. If this cannot be done clearly, a new ABN must be prepared.

We do not feel that it is appropriate to cross out those items that the beneficiary chooses not to receive without further action. This does not allow the beneficiary to choose an option from Section G of the form. In the scenario where there are multiple services listed on the ABN and the beneficiary chooses to receive some but not all of the services, a new ABN should be created; therefore allowing the beneficiary to choose Option 1 on the form for the services that they do not want to receive and either Option 2 or 3 on the other form for those services that they want to receive.

a. Option 1

We request that CMS clarify their intent regarding the use of Option 1. If this is an option that the beneficiary can choose for statutorily excluded services, how would providers bill for a coverage decision? Currently statutorily excluded services are reported as non-covered and Medicare Contractors do not review these services to determine coverage. If providers were to report statutorily excluded services as covered, how would Medicare Contractors know that the provider recognizes these services as non-covered and is not seeking reimbursement from the Medicare program?

b. Option 2

We request that CMS clarify their intent regarding use of Option 2. Can beneficiaries choose this option for statutorily excluded services and also those services that are not medically necessary according to a local coverage decision or national coverage decision? If a beneficiary chooses Option 2 for a service that is not covered according to a local coverage decision or national coverage decisions, the provider would be making the ultimate coverage decision as no claim would be submitted to the Medicare contractor.

From an editorial consistency perspective, we suggest changing the statement, "You may ask to be paid now as I am responsible for payment" to "I understand that I may be asked to pay now as I am responsible for payment."

c. Option 3

In order to provide clear guidance to the beneficiary, we suggest that the statement "I understand with this choice I am not responsible for payment," be revised to read "I understand that with this choice I will not receive the service, I am not responsible for payment . . ."

VI. Additional Information

To clarify the Medicare coverage decision process, we suggest changing the language in the Additional Information section from "This notice gives our opinion, not an official Medicare decision" to "Based on Medicare coverage guidelines, this notice gives our opinion and is not an official Medicare decision. Please note that Medicare does not make pre-service coverage decisions."

VII. Burden Estimate

We believe the Burden Estimate is understated in several aspects. While we do not disagree with the seven minutes on average to deliver an ABN, but do not feel that the estimate accurately includes all aspects of the process. In addition to delivering the ABN, there are additional steps during

the billing and collection process that are affected by the ABN. We believe that each claim that includes services for which an ABN has been obtained, takes an additional five minutes to process by the provider. Also, if Medicare denies the ABN service, the provider will incur additional costs to collect the funds from the beneficiary, including producing patient billing statements and follow-up phone calls.

Also, the estimated volume of ABNs delivered is based on the current ABN form and does not appear to be inclusive of the volume of NEMBs delivered.

We would request that the Burden Estimate be recalculated taking these points into consideration.

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We appreciate the opportunity to comment on this information collection activity and hope that the agency carefully considers the comments in this letter. If appropriate, we would welcome the opportunity to meet, at your convenience, to discuss our views. If you have any questions, please feel free to contact me or Jeffrey Micklos of my staff at (202) 624-1500.

Respectfully submitted,



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